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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/935,455	08/22/2001	Matthew O' Keefe	449142000120	9593
25226	7590	08/10/2004		
MORRISON & FOERSTER LLP 755 PAGE MILL RD PALO ALTO, CA 94304-1018			EXAMINER BEISNER, WILLIAM H	
			ART UNIT	PAPER NUMBER
			1744	

DATE MAILED: 08/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/935,455

Applicant(s)

O' KEEFE ET AL.

Examiner

William H. Beisner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 May 2004 and 18 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 10-19 and 24-66 is/are pending in the application.
- 4a) Of the above claim(s) 1, 10-19 and 24-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31-66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5/18/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group II, claims 31-54, in Paper No. 12 is acknowledged.
2. Claims 1, 10-19 and 24-30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 12.

Information Disclosure Statement

3. The information disclosure statement filed 18 May 2004 has been considered and made of record.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

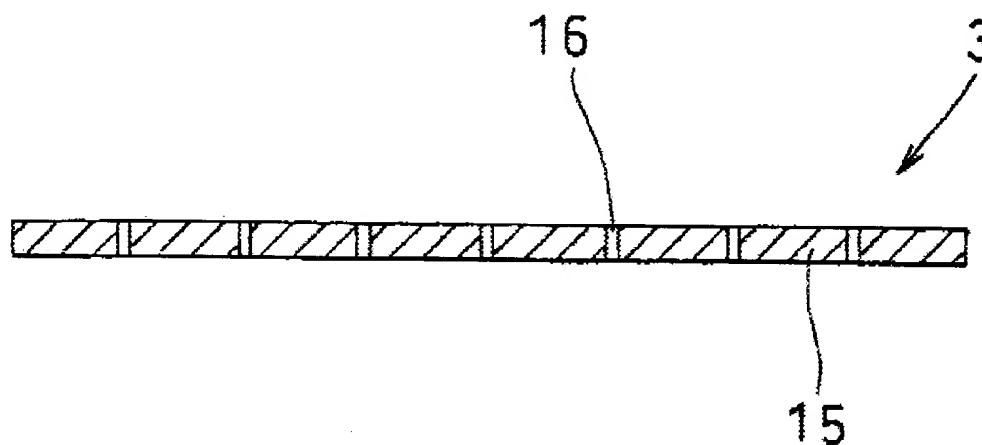
A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 59 and 61 are rejected under 35 U.S.C. 102(b) as being anticipated by Yamamoto et al.(US 6,071,702).

The reference of Yamamoto et al. discloses a substrate (15) that defines a plurality of sample chambers (16) (See Figure 3 reproduced below). The sample chambers (16) extend through the substrate (15); comprise one or more walls and opening at each end; and are capable of holding a sample such that liquid sample is held within the chamber and does not intermix with a liquid sample in another chamber; and includes a nucleic or protein probe within the chamber (See column 1, lines 60-63). Note the sheet substrate (15) may be 100microns to 2mm thick and the through holes is about 10-100 microns in diameter resulting in a height-to-width ratio that encompass less than or equal to "2:1" or "1:1".

FIG. 3



Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 31-55, 60, 62, 64 and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hunter (WO 99/34920) in view of Garyantes (US 6,565,813 or WO 99/39829) and Yamamoto et al.(US 6,071,702).

With respect to claim 31, the reference of Hunter discloses an apparatus for containing multiple micro-volume liquid samples comprising a substrate (10), wherein the substrate defines a plurality of sample chambers (12), wherein each sample chamber: (a) extends through the substrate (10), (b) comprises one or more walls and an opening at each end, and (c) holds a

sample such that the sample is in the form of a thin film such that a liquid sample present in one sample chamber does not intermix with a liquid sample present in another sample chamber (See column pages 4-6 and Figure 1).

While the reference of Hunter discloses that substrate (10) can be made of a glass, plastic, quartz material or metal (See page 6, lines 27-34), the instant claims differ by reciting that the substrate is made of titanium.

The references of Garyantes disclose a device for holding multiple micro-volume liquid samples wherein the samples are held within the sample chambers by surface tension (See the abstract of both references). The reference of Garyantes additionally discloses that the sample holding substrate can be made from a number of known materials including titanium (See page 41, lines 1-7 of the PCT reference and column 26, lines 41-49, of the US Patent reference).

In view of this teaching and in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ titanium as the substrate for the device disclosed by the reference of Hunter for the known and expected result of providing an art recognized equivalent for supporting multiple micro-volume liquid samples. Use of corrosion resistant titanium would be advantageous over glass, plastic or quartz since it would not be as fragile as a glass, plastic or quartz substrate.

Claim 31 further differs by reciting a height to width ration not disclosed by the reference of Hunter.

The reference of Yamamoto et al. discloses a substrate known in the art for contacting a sample with a reagent held in a through hole wherein the ratio of the height of the substrate to the

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diameter or width of the through hole is within the claim limitations of a height-to-width ratio that encompass less than or equal to "2:1" or "1:1".

In view of this teaching and in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ through holes within the claimed limitations as suggested by the reference of Yamamoto et al. for the known and expected result of providing an art recognized means for contacting a sample with an immobilized reagent. The exact dimensions of the substrate and through hole would have been obvious to one of ordinary skill in the art based on design considerations such as the material of the substrate and/or properties of the liquid sample to be contacted with the reagent within the through hole.

With respect to claims 32, 48, 61 and 62, the reference of Yamamoto et al. suggests a 1:1 ration of height to width, a substrate 100 microns thick with a 100 micron through hole.

With respect to claims 33 and 37-42, the substrate (10) is constructed of a hydrophilic core material (26,42) and the top and bottom surfaces include hydrophobic material, which forms hydrophobic annular rings along the wall of the chamber (28,40)(See Figure 5 which depicts two hydrophobic rings along the wall of the chamber and defines one non-hydrophobic ring therebetween.

With respect to claims 34-36, the substrate has upper and lower surfaces and the sample chambers have the shape of a right circular cylinder with an axis perpendicular to the faces of the substrate (See Figure 1). The substrate (10) includes through holes (12) that may be circular right cylinders or have rectangular cross-sections (See page 4).

With respect to claims 43-45, 49 and 64, the reference of Yamamoto et al. suggests the use of a hybridization probe affixed to the substrate.

With respect to claims 46, it would have been obvious to one of ordinary skill in the art to clean and/or sterilize the device prior to use for the known and expected result of eliminating any contaminating material which could interfere with the amplification reaction and/or compromise the integrity of the assay.

With respect to claim 47, while the claim recites a “kit”, the claim is structurally the same as that of claim 31 and therefore is obvious for the same reasons as set forth with respect to claim 31.

With respect to claims 50, 51 and 66, whether the device is manufactured with a hydrophobic substance or the substance is applied prior to use would have been merely an obvious matter in design choice while still providing the required hydrophobic coating on the substrate surfaces.

With respect to claims 52-54, while the reference discloses the use of reagents and an environment for performing the assay, the reference is silent as to the packaging of these items as a kit. However, it would have been obvious to one of ordinary skill in the art to provide all of the components (i.e., the test device, the reagents, liquid transfer devices, and thermal cycling device) required to perform the device as a kit for the known and expected result of facilitating the performance of the assay by providing all required components for performing the assay.

With respect to claim 55, the reference of Hunter discloses a sample holding substrate with circular openings for holding the samples wherein raised features (8) can circumscribe the openings (See page 5, lines 8-11).

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 59-61 and 63 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 15, 29, 46, and 18 of copending Application No. 09/789,601. Although the conflicting claims are not identical, they are not patentably distinct from each other because With respect to instant claim 59, claim 15 of Application '601 anticipates instant claim 59 since a PCR primer meets the claim limitation recited in claim 59 of "further comprising reagents sufficient to carry out a nucleotide sequencing reaction, a hybridization reaction, or a polynucleotide amplification reaction". With respect to instant claim 60, claim 29 of Application '601 encompasses a titanium substrate. With respect to instant claim 61, claim 46 of Application '601 encompasses a height to width ratio recited in instant claim 61. With respect to instant claim 63, claim 18 of Application '601

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encompasses the use of a hydrophobic annular ring to define two hydrophilic regions on the wall of the chamber.

12. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

13. Claims 31-58, 62 and 64-66 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 15, 16, 18-28, 30-42 and 44-47 of copending Application No. 09/789,601 in view of Garyantes (US 6,565,813 or WO 99/39829) and Yamamoto et al.(US 6,071,702).

Claims 15, 16, 18-28, 30-42 and 44-47 of application '601 encompass an apparatus and kit that is essentially the same as that instantly claimed in claims 31-58, 62, 64 and 65 of the instant application.

The instant claims differ by further reciting that the substrate is made of a titanium material.

The references of Garyantes disclose a device for holding multiple micro-volume liquid samples wherein the samples are held within the sample chambers by surface tension (See the abstract of both references). The reference of Garyantes additionally discloses that the sample holding substrate can be made from a number of known materials including titanium (See page 41, lines 1-7 of the PCT reference and column 26, lines 41-49, of the US Patent reference).

In view of this teaching and in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ titanium as the substrate for the device disclosed by the reference of Hunter

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for the known and expected result of providing an art recognized equivalent for supporting multiple micro-volume liquid samples. Use of corrosion resistant titanium would be advantageous over glass, plastic or quartz since it would not be as fragile as a glass, plastic or quartz substrate.

With respect to the claimed height to width ratio, the reference of Yamamoto et al. discloses a substrate device for contacting a sample liquid with a reagent within a sample holding through hole wherein the substrate and through hole can be of dimensions that meet the instant claim limitations. Note the sheet substrate (15) may be 100microns to 2mm thick and the through holes is about 10-100 microns in diameter resulting in a height-to-width ratio that encompass less than or equal to "2:1" or "1:1" (See column 1, lines 60-63).

In view of this teaching and in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ through holes within the claimed limitations as suggested by the reference of Yamamoto et al. for the known and expected result of providing an art recognized means for contacting a sample with an immobilized reagent. The exact dimensions of the substrate and through hole would have been obvious to one of ordinary skill in the art based on design considerations such as the material of the substrate and/or properties of the liquid sample to be contacted with the reagent within the through hole.

This is a provisional obviousness-type double patenting rejection.

Response to Arguments

14. Applicant's arguments, see pages 11-14, filed 05 May 2004, with respect to the 35 USC 103 rejection over the combination of the references of deMacario and Garyantes et al. have been fully considered and are persuasive. The rejection of the claims in view of this combination of references has been withdrawn.

15. Applicant's arguments with respect to claims 31-66 have been considered but are moot in view of the new ground(s) of rejection. Note, applicants' response includes amendments to independent claims 31 and 47 which contain newly recited claim limitations and includes new claims 59-66. As a result, new grounds of rejection have been made to address the new claim limitations not encompassed by the combination of the references of Hunter et al. and Garyantes.

With respect to applicants' comments concerning the use of Garyantes as a reference suggesting the use of titanium as a substrate material, while the reference does not disclose a substrate with through holes, the reference suggests the use of titanium as a material as a substrate for throughput screening assays. The references of Hunter and Yamamoto et al. are both drawn to screening assay devices and both disclose that metal materials can be used as a substrate material. As a result, it clearly would have been within the level of skill in the art to employ titanium as a substrate material for the reasons set forth in the obviousness rejections above.

Conclusion

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16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

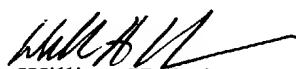
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert J. Warden can be reached on 571-272-1281. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



William H. Beisner
Primary Examiner
Art Unit 1744

WHB